

June 21, 2001

John L. Festa, Ph.D.
Senior Scientist
American Forest and Paper Association
1111 Nineteenth Street, N.W.
Suite 800
Washington, D.C. 20038

Dear Dr. Festa:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the test plan for Spent Pulping Liquor, posted on the ChemRTK Web Site on February 20, 2001. I commend The American Forest and Paper Association for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

As explained in the enclosed Comments, EPA agrees with the planned biodegradation testing following test substance neutralization but believes that the plan to measure vapor pressure and boiling point will provide little useful information. The sponsor needs to explain why fugacity modeling should not be included in the test plan.

EPA also requests the identification of a specific test guideline/method/protocol for the *in vitro* mammalian cell culture assays and, for the ecological effects testing, asks that the sponsor perform an analytical characterization of the test material at test termination.

As with other submissions where the available data are either inadequate or insufficiently documented, this case will remain open until adequate documentation is in hand.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that the Association advise the Agency, within 60 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-260-3470. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsc hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Spent Pulping Liquor

SUMMARY OF EPA COMMENTS

The sponsor, The American Forest & Paper Association HPV Consortium, submitted a Test Plan to EPA, dated January 31, 2001, for Spent Pulping Liquor (CAS # 66071-92-9). EPA posted the submission on the ChemRTK HPV Challenge Web site on February 20, 2001.

EPA has reviewed this submission and has reached the following conclusions:

1. EPA agrees that because of the substance's highly complex, variable composition and its strongly alkaline nature (pH 11.5 to 13.5), most of the SIDS data would be difficult to generate.
2. Physicochemical and Environmental Fate Data. EPA agrees with the planned biodegradation testing following test substance neutralization but believes that the plan to measure vapor pressure and boiling point will provide little useful information. The sponsor needs to explain why fugacity modeling should not be included in the test plan.
3. Health Endpoints: EPA agrees with the proposed Test Plan, but requests the identification of a specific test guideline/method/protocol for the *in vitro* mammalian cell culture assays.
4. Ecotoxicity. EPA agrees with the proposed Test Plan, but asks that the sponsor perform an analytical characterization of the test material at test termination.

EPA COMMENTS ON THE SPENT PULPING LIQUOR CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

EPA does not agree with the test plan that measuring vapor pressure and boiling point will provide useful information.

Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

EPA agrees with the test plan, except that it did not discuss transport/distribution (fugacity). The sponsor needs to remedy the omission.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

EPA agrees with the test plan. For the *in vitro* genetic toxicity testing *in bacterial* and mammalian cell cultures, with pH adjustment of the test substance to ensure survival of the test organisms, the sponsor needs to specify which mammalian cell culture test will be performed.

Ecological Effects.

EPA agrees with the sponsor's plan to evaluate toxicity to fish, daphnia, and algae following pH

adjustment of the test substance to ensure survival of the test organisms. Given that many discrete lower molecular-weight entities are expected in the pre-neutralized substance, EPA believes that at the completion of testing, the test substance should be characterized analytically to the extent possible, at least to identify any major components.

SPECIFIC COMMENTS ON ROBUST SUMMARIES

No robust summaries were submitted.